



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,229	10/27/2006	Selwayan Saini	P08813US00/MP	5464

881 7590 04/21/2008
STITES & HARBISON PLLC
1199 NORTH FAIRFAX STREET
SUITE 900
ALEXANDRIA, VA 22314

EXAMINER

WALLENHORST, MAUREEN

ART UNIT	PAPER NUMBER
----------	--------------

1797

MAIL DATE	DELIVERY MODE
-----------	---------------

04/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/562,229	Applicant(s) SAINI ET AL.	
	Examiner Maureen M. Wallenhorst	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1797

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.
2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1797

5. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Say et al (US 6,134,461, submitted in the Information Disclosure Statement filed on October 27, 2006) in view of Saini et al (WO 00/20855, also submitted in the IDS filed on October 27, 2006).

Say et al teach of an electrochemical sensor and a method for using the sensor to determine analytes in body fluids such as interstitial fluid and blood. The analytes detected include glucose, lactate or oxygen. The sensor can be used for the in vitro determination of the presence and/or level of an analyte in a body fluid, or can be used for the in vivo determination of an analyte by implantation of the sensor into the arterial or venous system of an individual. The sensor 42 comprises a substrate 50 on which is printed a working electrode 58, a counter electrode 60 and/or at least one reference electrode 62. The electrodes are formed using conductive traces 52 disposed on the substrate 50. A sensing layer 64 is often formed proximate to the working electrode 58 to facilitate the electrochemical detection of the analyte and determination of its level in the sample fluid. A control unit 44 serves to operate the sensor, and a processing unit 45 serves to analyze the measurements from the sensor 42. Say et al teach that an interferent-eliminating layer may be included in the sensor. The interferent-eliminating layer may include a NafionTM material incorporated into a polymeric matrix that is coated over the electrodes. The NafionTM material reduces the permeability of the interferent-eliminating layer to ionic interferents having the same charge as the ionic components to be detected. For example, negatively charged compounds may be incorporated into the interferent-eliminating layer to reduce the permeation of negative species in the body fluid being analyzed. The NafionTM material prevents the penetration of one or more interferents into the region around the working electrode 58. To use the sensor, a body fluid sample is drawn into the sensor using a

Art Unit: 1797

wicking or capillary action so that it contacts the electrodes. A potential is applied across the working and counter electrodes 58, 60 so that an electrical current will flow. The current is a result of the electrolysis of the analyte, and a measurement of the current provides an indication of the level of the analyte in the body fluid sample. See figures 2 and 8, lines 59-66 in column 4, columns 5-6, lines 1-30 in column 7, lines 1-33 in column 22 and lines 38-59 in column 25 of Say et al. Say et al fail to teach that multiple analytes in a body fluid sample can be measured simultaneously using the sensor by applying a varying potential to the electrochemical sensor, and analyzing the resulting electrochemical measurements using a multivariate calibration technique.

Saini et al (WO 00/20855) teach of an electrochemical method for analyzing multiple analytes in a sample simultaneously by using dual pulse staircase voltammetry (DPSV) in combination with an enhanced information recovery technique such as artificial neural networks. In the method, a sample containing multiple analytes such as ethanol, fructose and glucose is applied to an electrochemical sensor having a working, a counter and a reference electrode therein, and an electrode cleaning pulse is applied to the sensor. The first pulse is applied at a relatively high potential to form an oxide layer on the electrode surface, which is then removed, along with any material adsorbed to the electrode, by a negative pulse. A stepwise increasing potential is then applied to the sensor, and current is measured after each step. To facilitate oxide formation and dissolution, analysis is usually performed at a gold or platinum electrode in a solution of relatively low or high pH. The electrochemical response of the mixture is then subjected to virtual separation using a multivariate calibration technique known as an artificial neural network. Saini et al teach that the method involving DPSV followed by data analysis

Art Unit: 1797

using an artificial neural network allows a mixture of aliphatic compounds to be simultaneously measured by yielding a spectra-like response containing numerous peaks corresponding to the different compounds present in the sample. See the abstract, pages 5-6 and 9-10, and the claims in Saini et al.

Based upon the combination of Say et al and Saini et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to apply a varying potential to the electrochemical sensor taught by Say et al followed by an analysis of the resulting data using a multivariate calibration technique such as an artificial neural network since Saini et al teach that the application of a varying potential in incremental steps to a similar type of electrochemical sensor followed by data analysis using an artificial neural network allows multiple analytes in a sample to be simultaneously measured accurately, thus obviating the need for a separate, specialized sensor for each individual type of analyte found within the body fluid sample analyzed using the method of Say et al.

6. Applicant's arguments filed January 22, 2008 have been fully considered but they are not persuasive.

Applicants' arguments concerning the previous objection to the abstract made in the last Office action mailed on September 20, 2007 are persuasive, and therefore, the objection to the abstract has been withdrawn. The previous objection to the specification concerning the use of the trademark NAFION, and the previous rejection of the claims under 35 USC 112, second paragraph made in the last Office action are also withdrawn in view of Applicants' amendments made to the specification and claims.

Applicants argue the rejection of the claims under 35 USC 103 as being obvious over Say et al in view of Saini et al by stating that Say et al teach that the NAFION layer in the electrochemical sensor is for removing interferants in the sample analyzed, whereas the NAFION coating of the electrodes in the sensor of the instant invention serves to enhance the detection of glucose by providing well-resolved redox peaks due to the ionic interaction between charged glucose intermediates and charged SO₃ groups bonded to the NAFION polymer. Therefore, Applicants argue that the NAFION membranes of the instant invention bring about significant and unexpected advantages to glucose detection over what is taught by Say et al. Applicants' arguments are not found persuasive since the primary reference to Say et al teaches of most of the limitations in claim 1, namely the steps of adding a sample of fluid (i.e. interstitial fluid or blood) to an electrochemical cell containing a working, a reference and a counter electrode, wherein the electrodes are coated with a membrane of NAFION in one embodiment, applying a potential to the working electrode thereby causing an electrochemical redox reaction of glucose in the sample at the electrodes, measuring an electrochemical outcome of the sensor and providing an output signal related to the presence and concentration of glucose in the sample analyzed. With regards to independent claim 1, Say et al only fails to teach of applying a varying potential to the electrodes. However, the secondary reference to Saini et al clearly teaches the application of a varying potential in an electrochemical sensor for the advantage of detecting multiple analytes in a sample simultaneously, thus obviating the need for a separate, specialized sensor for each individual type of analyte found within a body fluid. It is also noted that although Say et al teach that the NAFION interferant-eliminating layer is optional, it nevertheless is an embodiment of the electrochemical sensor taught by Say et al, and the

Art Unit: 1797

evidence of obviousness must include all reasonable interpretations of an invention including non-preferred embodiments. In addition, although Say et al do not teach that the NAFION coating of the electrodes in the sensor serves to provide an enhanced detection of glucose in the same manner as the instant invention, the reason for adding the coating of NAFION to the electrodes in the Say et al reference does not have to be the same as Applicants' reason for including the NAFION coating. The mere discovery or recognition of an inherent property of a material (i.e. the NAFION coating in the electrochemical cell taught by Say et al) cannot give patentability to the already known material taught by Say et al. See *In re Mod*, 161 USPQ 281. Similarly, the mere difference in the reason for adding or using a material in combination with another material (i.e. the NAFION coating of the electrodes in Say et al) is not patentable.

For all of the above reasons, Applicants' arguments are not found persuasive.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1797

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1797

mmw

April 15, 2008

/Maureen M. Wallenhorst/

Primary Examiner, Art Unit 1797